

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Paul DiCarlo et al.	Art Unit	: 1773
Serial No.	: 10/791,103	Examiner	: Leszek B. Kiliman
Filed	: March 2, 2004	Conf. No.	: 2432
Title	: EMBOLIC COMPOSITIONS		

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**BRIEF ON APPEAL**

The Appeal Brief fee of **\$510** is enclosed. Appellant files a Notice of Appeal herewith.

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Docket 01194-823002.

**(1.) Real Party In Interest**

The real party in interest in the above application is BOSTON SCIENTIFIC SCIMED, INC., a corporation of Minnesota, having a place of business at One Scimed Place, Maple Grove, MN 55311-1566.

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I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: July 14, 2008

**(ii.) Related Appeals and Interferences**

Appellant is not aware of any appeals or interferences related to the above-identified patent application.

**(iii.) Status of Claims**

This is an appeal from the rejections of claims 1-10, 17, 25-27, and 29-39 provided by the Examiner in a non-final Office Action dated April 11, 2008, a non-final Office Action dated May 16, 2007, a Final Office Action dated June 1, 2006 and an Advisory Action dated January 22, 2007. Claims 1-10, 17, 25-27, and 29-39 have been twice rejected. Each of claims is currently rejected, and is presented for appeal.

**(iv.) Status of Amendments**

All amendments have been entered. Appellant files a Notice of Appeal herewith.

**(v.) Summary of Claimed Subject Matter**

The invention relates to embolic compositions and methods of using the compositions. (See, e.g., Application, p. 1, line 9.) In one aspect, the invention features a composition that includes a generally spherical embolic particle that includes a shape memory material. (See, e.g., id., p. 1, lines 21-22, p. 4, lines 27-28, p. 11, lines 12-15, and Figs. 1A, 18, and 19.)

In certain embodiments, the composition includes the generally spherical embolic particles in a vessel with a suitable carrier, such as saline. (Id., p. 4, lines 25-27 and Fig. 1A.) A change in the shape of the particle can be selectively triggered to facilitate treatment, such as

embolization. (Id., p. 4, lines 28-31 and Fig. 1B.)

Claim 1, which is the only claim in independent form, reads as follows:

A composition comprising an embolic particle comprising a shape memory material, wherein the particle is generally spherical.

Thus, all the claims require a generally spherical embolic particle that includes a shape memory material.

**(vi.) The Grounds of Rejection to be Reviewed on Appeal**

Claims 1-10, 17, 25-27, and 29-39 were rejected under 35 U.S.C. §102(b) as being anticipated by Kamiya et al., U.S. Patent No. 5,192,301 ("Kamiya") and A. Laurent, "Materials and Biomaterials for Interventional Radiology", *Biomed. & Pharmacother.* 1998: 52: 76-88 ("Laurent").

**(vii.) Argument**

For the purposes of this appeal only, claims 1-10, 17, 25-27, and 29-39 stand or fall together. Claim 1 is representative of this group of claims.

**Kamiya**

Claims 1-10, 17, 25-27 and 29-39 cover compositions that include a generally spherical embolic particle. While the Examiner points to certain portions of Kamiya in rejecting these claims, none of these portions of Kamiya explicitly disclose a generally spherical embolic particle. Nor do any other portions of Kamiya explicitly disclose a generally spherical embolic particle. Kamiya also does not inherently disclose a generally spherical embolic particle. As

stated by the United States Court of Appeals for the Federal Circuit Electro Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052 (Fed. Cir. 1994):

The mere fact that a thing *may result* from a given set of circumstances is insufficient to prove anticipation. (citations omitted; emphasis original).

Rather, one asserting that a reference inherently discloses certain subject matter must prove that the features are:

necessarily present [in the prior art reference] and that it would be so recognized by persons of ordinary skill. (Id.)

Here, the Examiner has not satisfied the requisite legal standard. Kamiya discloses numerous different articles having various shapes. (See, e.g., Kamiya at Figs. 1-29.) None of these articles could be interpreted as being generally spherical, let alone a generally spherical embolic particle. Accordingly, upon reading Kamiya, a person of ordinary skill in the art would not recognize that any of Kamiya's articles are necessarily generally spherical, and certainly would not recognize that any of Kamiya's articles are necessarily a generally spherical embolic particle.

On previous occasions, Appellant argued that Kamiya does not disclose a generally spherical embolic particle. (Amendment mailed March 8, 2006, p. 7 and Reply mailed July 10, 2006, pp. 1 and 2). It is Appellant's understanding that, under such circumstances, the Examiner has a duty to answer the substance of this argument. (See, e.g., M.P.E.P §707.07(f).) But, despite the fact that Appellant has made specific reference to the subject matter that Kamiya fails to disclose and has cited caselaw to support this argument, the Examiner has failed to engage

Appellant in any meaningful way on this issue. Rather in reply to Appellant's arguments, the Examiner has simply said:

The amendments and remarks filed by applicants in [the Amendment mailed March 8, 2006] have been fully considered. The arguments have not been persuasive. The Examiner believes that the rejections are still proper and are maintained. (Office Action mailed June 1, 2006)

and:

The arguments have not been persuasive. The examiner believes that the rejections are proper. (Advisory Action mailed January 22, 2007.)

and:

The limitation that the particle is "generally spherical" is believed to be inherently disclosed in the applied prior art. (Office Action mailed April 11, 2008.)

Indeed, in making the rejection, the substance of the basis of the rejection has been a single sentence that is not even two complete lines long, which the Examiner first stated in the Office Action on December 12, 2005, then repeated verbatim in the Final Office Action mailed June 1, 2006, and further repeated verbatim in the Office Action mailed May 16, 2007. (Office Action mailed December 12, 2005, p. 2, Final Office Action mailed June 1, 2006, p. 2, and Office Action mailed May 16, 2007, p. 2.) While in the Office Action mailed April 11, 2008, the Examiner changed the language somewhat, the substance of the rejection remains unchanged. Appellant therefore respectfully submits that the Examiner has not properly met his burden in maintaining this rejection.<sup>1</sup> Because Kamiya fails to explicitly or inherently disclose each and

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<sup>1</sup> Appellant raises further general concerns regarding the manner in which the examination of this application has been handled. As an example, despite the fact that that Appellant filed an early reply to the Final Office Action mailed June 1, 2006, the Advisory Action was not mailed until January 22, 2007 -- nearly six and a half months

every limitation of Appellant's claims 1-10, 17, 25-27 and 29-39, the Examiner erred in rejecting claims 1-10, 17, 25-27 and 29-39 under 35 U.S.C. §102(b). Appellant therefore requests reversal of the rejection of claims 1-10, 17, 25-27 and 29-39.

Laurent

The United States Court of Appeals for the Federal Circuit has stated that "[a]nticipation' requires that the identical invention was already known to others, that is, that the claimed invention is not new." (C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1360 (Fed. Cir. 1998).) Laurent provides an analysis of many different types of interventional devices, including embolic particles (see Laurent at 80) and stents that are formed of Nitinol, a shape memory material (see Laurent at 78). But Laurent's discussion of embolic particles in one section of his article and of Nitinol in a different section of his article does not make the identical invention of an embolic particle including a shape memory material known to others, and thus does not anticipate claims 1-10, 17, 25-27, and 29-37 under 35 U.S.C. § 102(b).

For example, in Ecolochem, Inc. v. Southern California Edison Co., the Federal Circuit held that claims covering a deoxygenation process including a first step of contacting a liquid containing dissolved oxygen and hydrazine with a bed of activated carbon, and a second step

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later. The Advisory Action was mailed so late (and only after repeated phone calls to the Examiner and the Supervisory Patent Examiner) that Appellant had to go through the inconvenience and substantial financial cost of mailing the Notice of Appeal and paying substantial extension fees while waiting to receive the Advisory Action. As another example, on February 28, 2007, Appellant filed a Request for Continued Examination with an Information Disclosure Statement to cite a single reference. Although the USPTO PAIR website clearly indicates that the Information Disclosure Statement and the single reference were received, in the Office Action mailed May 16, 2007, responsive to the Request for Continued Examination, the Examiner failed to consider the single reference (i.e., an initialed PTO Form 1449 was not attached to the Office Action mailed May 16, 2007, nor was the box checked on page 2 of this Office Action to indicate that the Examiner was attaching the initialed the PTO Form 1449). After more than five discussions with the Examiner's Supervisory Patent Examiners (they have changed over time), it still took almost a year for Appellant to receive a 1449 with the Examiner's initials, indicating the Examiner considered the reference.

including passing the liquid through a strong acid cation exchange resin and a strong base anion exchange resin, were not anticipated by a reference that separately disclosed these steps, but that did not disclose one process including both of these steps. (See *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1366-69 (Fed. Cir. 2000).) In one section of the reference, the authors disclosed a deoxygenation process including deoxygenating water by hydrogen, and then passing the deoxygenated water through a mixed bed (an acid cation exchange resin and a base anion exchange resin). (See *id.*) In a separate section of the reference, the authors disclosed a deoxygenation process including deoxygenating water by hydrazine. (See *id.*) However, the authors did not disclose subsequently passing the deoxygenated water through a mixed bed. (See *id.*) The court agreed with another court's earlier decision that "[n]othing in the . . . reference expressly teaches the use of a mixed bed ion exchange resin following the hydrazine/carbon process", and held that the reference therefore did not anticipate the claims. (See *id.* at 1368-69.) Similarly, Laurent's discussion of a Nitinol stent in one section of his article, and of embolic particles in a different section of his article, is not an anticipatory disclosure of an embolic particle including a shape memory material under 35 U.S.C. § 102(b).

Appellant made this argument at pages 8 and 9 of their Amendment mailed March 8, 2006. However, despite Appellants setting forth this legally sound argument regarding why, under the appropriate legal standards, Laurent does not disclose the subject matter covered by claims 1-10, 17, 25-27 and 29-39, here again the Examiner failed to engage Appellant in any meaningful way, and instead simply relied on the same language quoted above with regard to the rejection based on Kamiya to maintain the rejection based on Laurent. Accordingly, like with Kamiya, Appellant believes that the Examiner failed to meet his burden in maintaining the

rejection. (See, e.g., M.P.E.P §707.07(f).) Indeed, in rejecting the claims based on Laurent, the substance of the Examiner's rejection has at times been five words:

See the whole Laurent article. (Office Action mailed December 12, 2005, p. 2, Final Office Action mailed June 1, 2006, p. 2, and Office Action mailed May 16, 2007, p. 2.)

In the most recent Office Action, the Examiner said:

The limitation that the particle is "generally spherical" is believed to be inherently disclosed in the applied prior art. (Office Action mailed April 11, 2008.)

In view of the foregoing, Appellant requests reversal of the rejection of claims 1-10, 17, 25-27 and 29-39 under 35 U.S.C. §102(b) as being anticipated by Laurent.

#### Conclusion

Appellant submits, therefore, that Claims 1-10, 17, 25-27 and 29-39 are allowable over the cited art. Therefore, the Examiner erred in rejecting Appellant's claims and should be reversed.

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Respectfully submitted,

Date: July 14, 2008

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### **Appendix of Claims**

1. (Previously presented) A composition comprising an embolic particle comprising a shape memory material,  
  
wherein the particle is generally spherical.
2. (Original) The composition of claim 1, wherein the shape memory material comprises a polymer.
3. (Original) The composition of claim 2, wherein the polymer is a material selected from the group consisting of polyurethane, polynorbornene, polymethylmethacrylate, poly(vinyl chloride), polyethylene, polyisoprene, styrene-butadiene copolymer, a rubber, and a photocrosslinkable polymer
4. (Original) The composition of claim 1, wherein the shape memory material comprises an alloy.
5. (Original) The composition of claim 4, wherein the alloy is a material selected from the group consisting of a nickel-titanium alloy.
6. (Original) The composition of claim 1, wherein the particle is non-bioabsorbable in a body.

7. (Original) The composition of claim 1, wherein the particle comprises a therapeutic agent.

8. (Original) The composition of claim 7, wherein the particle defines a cavity, and the therapeutic agent is in the cavity.

9. (Original) The composition of claim 1, wherein the particle comprises a radiopaque material.

10. (Original) The composition of claim 9, wherein the radiopaque material is selected from the group consisting of gold, tantalum, platinum, and tungsten.

11-16. (Cancelled).

17. (Original) The composition of claim 1, wherein the particle has a groove.

18-24. (Cancelled).

25. (Previously presented) The composition of claim 1, wherein the particle comprises a portion capable of dissolving in a body.

26. (Original) The composition of claim 1, wherein the particle further comprises a second material that does not include a shape memory material.

27. (Previously presented) The composition of claim 26, wherein the second material is selected from the group consisting of polyester, nylon, polytetrafluoroethylene, polypropylene, poly-paraphenylene terephthalamide, silk, collagen, hair, and alginate.

28. (Cancelled).

29. (Original) The composition of claim 1, comprising a plurality of embolic particles, wherein at least one of the particles comprises the shape memory material.

30. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different shape than a particle in the plurality of embolic particles.

31. (Previously presented) The composition of claim 29, comprising the generally spherical particle and a non-spherical particle.

32. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different size than a particle in the plurality of embolic particles.

33. (Original) The composition of claim 29, further comprising a second plurality of embolic particles, a particle in the second plurality having a different hardness than a particle in the plurality of embolic particles.

34. (Original) The composition of claim 1, further comprising a second, non-solid embolic material.

35. (Original) The composition of claim 34, wherein the second embolic material is in the form of a liquid, a gel, or a foam.

36. (Original) The composition of claim 1, wherein the particle comprises a material capable of increasing in volume upon exposure to a predetermined stimulus.

37. (Original) The composition of claim 36, wherein the material comprises a hydrogel.

38. (Previously presented) The composition of claim 26, wherein the second material is selected from the group consisting of polyester, nylon, polytetrafluoroethylene, polypropylene, silk, collagen, hair, and alginate.

39. (Previously presented) The composition of claim 27, wherein the second material comprises polyethylene terephthalate.

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### **Evidence Appendix**

None.

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### **Related Proceedings Appendix**

None.